Application/Control Number: 10/520,961 Page 2

Art Unit: 3775

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 25th, 2009 has been entered.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show
every feature of the invention specified in the claims. Therefore, the end faces being
convex must be shown or the feature(s) canceled from the claim(s). No new matter
should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

Application/Control Number: 10/520,961 Page 3

Art Unit: 3775

of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abevance.

Double Patenting

3. Applicant is advised that should claim 1 be found allowable, claim 12 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim.
See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

- The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant repards as his invention.
- Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite
 for failing to particularly point out and distinctly claim the subject matter which applicant
 regards as the invention.
- 6. Claim 9 recites the limitation "the receiving head" in line 1. There is insufficient antecedent basis for this limitation in the claim. The examiner will interpret the limitation as the head of the bone anchoring element for examination purposes.

Application/Control Number: 10/520,961 Page 4

Art Unit: 3775

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all
obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

 Claims 1, 2, 4-8, and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernhardt (U.S. Patent 5,591,166) in view of Bjors (U.S. Patent 4,055,385).

Bernhardt discloses a device comprising a bone anchoring element (32), a threaded shaft (22), and a clamping means (48). The bone anchoring element defines a longitudinal axis and includes a head having a first end face. The threaded shaft includes a second end face facing the first end face of the bone anchoring element. The clamping means is screwed to the head of the bone anchoring element to prevent longitudinal separation between the bone anchoring element and the threaded element. Bernhardt further discloses a spherical articulation between the bone anchoring element and the threaded shaft, wherein contact between the end faces delimit, i.e. define, the movement of the threaded shaft relative to the bone anchoring element. Bernhardt fails to disclose the device further comprising a rotational linkage means. Bjors teaches a device comprising a first element (16) having a first end face (28 and the spherical surface defining the ball of the joint) and a second element (12) having a second end face (29 and the surface defining the entire receptacle for the ball), wherein a spherical articulation between the elements and a distance between the end faces delimits the

Art Unit: 3775

movement of the elements and provide multiple orientations relative to each other. Bjors teaches the device further comprising a rotational linkage means (see Figure 4) longitudinally positioned on the end faces of the elements outside the spherical articulation comprising a male geometrical form having a non-circular cross-section (the trapezoid shaped projection extending from surface 28) extending from the ball and a female geometrical form having a non-circular cross-section (the receptacle extending from surface 29), wherein both end faces include convex portions and flat portions in order to limit the movement between the elements relative to one another. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Bernhardt further comprising a rotational linkage means in view of Bjors in order to limit the movement between the bone anchoring element and the threaded shaft.

The device of Bernhardt as modified by Bjors discloses a device wherein the male geometrical form is located on the ball of the threaded element and the female geometrical form is located on the bone anchoring element. The device of Bernhardt as modified by Bjors discloses the invention as claimed except for male geometrical form being on the bone anchoring element and the female geometrical form being on the ball. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Bernhardt as modified by Bjors wherein the male geometrical form is on the threaded shaft and the female geometrical form is on the ball, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

Art Unit: 3775

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bernhardt
 (U.S. Patent 5,591,166) in view of Bjors (U.S. Patent 4,055,385) further in view of
 Mullane (U.S. Patent 5,628,740).

The device of Bernhardt as modified by Bjors discloses the invention as claimed except for the outer surface of the head of the bone anchoring element forming a grip nut. Mullane discloses a device comprising a bone anchoring element (22) having a head (86) with an outer surface that forms a grip nut in order to allow the use of leverage tools during implantation of the device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Bernhardt as modified by Bjors wherein the outer surface of the head of the bone anchoring element forms a grip nut in view of Mullane in order to allow leverage tools to be used during implantation of the device.

Response to Arguments

10. Applicant's arguments with respect to claims 1, 2, and 4-14 have been considered but are moot in view of the new ground(s) of rejection. The examiner has provided new grounds of rejection with new prior art references making the applications arguments moot.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant in the prior art.

Art Unit: 3775

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is (571)272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas Woodall/ Examiner, Art Unit 3775